## Zika test result scenarios with lab interpretation, caveats/comments, Zika case classification, and pregnancy registry

TEST TYPE	TEST RESULT	LAB INTERPRETATION <sup>1</sup>	CAVEATS/COMMENTS	ZIKA CASE CLASSIFICATION	PREGNANCY REGISTRY ELIGIBLE <sup>2</sup>
Zika PCR	Detected	Evidence of recent infection with Zika virus		<b>CONFIRMED ZIKA</b> , if meets clinical/epi criteria	Yes
Zika PCR	Not detected	No evidence of recent infection with Zika virus by RT-PCR	If collected >7 days after onset, virus may have declined below detectable levels. Serology should be performed.	Not a Zika case	No
Zika IgM antibody only	Not detected/equivocal	No evidence of recent infection with Zika virus by IgM antibody testing	If collected ≤7 days after onset (or last date of potential exposure if asymptomatic), IgM antibodies may not yet have reached detectable levels. If collected >12 weeks after exposure, IgM antibodies may have waned.	Not a Zika case	No
Zika IgM antibody only	Detected	Presumptive Zika positive	Current DCLS capability; positive results will be forwarded to CDC for confirmation (IgM antibodies and PRNT panel testing).	Not a Zika case; but cannot rule out Zika <sup>3</sup> . Confirmatory testing at CDC will determine Zika case classification.	Yes; further determination by PRNT, if available
Zika IgM antibody	Detected		If dengue IgM antibody is positive,		
Plaque-reduction neutralizing antibody titer (PRNT)	Detected  Detectable <sup>4</sup> Zika PRNT & Zika PRNT ≥4-fold higher than dengue or other flavivirus PRNT	Evidence of recent infection with Zika virus	may represent a dengue case. Please refer to the dengue case definition for possible classification as a dengue case.	CONFIRMED ZIKA, if meets clinical/epi criteria	Yes
Zika IgM antibody	Detected	Evidence of recent infection	Patient may have had dengue in the		
Dengue IgM antibody	Detected or unknown	with flavivirus. The identity of the infecting virus cannot be determined because of a lack of fourfold difference in neutralizing antibody test results between related viruses.	past, or Zika antibodies may be cross-reacting with dengue PRNT. If dengue IgM antibody is positive, may represent a dengue case. Please refer to the dengue case definition for possible classification as a dengue case.	Not a Zika case; but cannot rule out Zika <sup>3</sup>	Yes
Plaque-reduction neutralizing antibody titer (PRNT)	Detectable <sup>4</sup> Zika PRNT & Zika PRNT <b>not</b> ≥4-fold higher compared to dengue or other flavivirus PRNT				
Zika IgM antibody	Detected	Evidence of recent infection with flavivirus. The identity of the infecting virus cannot be determined because of a lack of fourfold difference in	Patient may have had dengue in the past, or Zika IgM antibodies may be cross-reacting with dengue PRNT.	PROBABLE ZIKA, if meets clinical/epi criteria	Yes
Dengue IgM antibody Plaque-reduction neutralizing antibody titer (PRNT)	Not detected or equivocal  Detectable <sup>4</sup> Zika PRNT &  Zika PRNT <b>not</b> ≥4-fold higher  compared to dengue or other				

	flavivirus PRNT	neutralizing antibody test results between related viruses.			
Zika IgM antibody Dengue IgM antibody Plaque-reduction neutralizing antibody titer (PRNT)	Not detected or equivocal  Not done	Unknown	This scenario may arise when commercial labs begin to test for Zika virus.	PROBABLE ZIKA, if meets clinical/epi criteria	Yes
Zika IgM antibody Dengue IgM antibody  Plaque-reduction neutralizing antibody titer (PRNT)	Detected Detected or unknown  Not done	Unknown	This scenario may arise when commercial labs begin to test for Zika virus.  If dengue IgM antibodies is positive, may represent a dengue case. Please refer to the dengue case definition for possible classification as a dengue case.	Not a Zika case; but cannot rule out Zika <sup>3</sup>	Yes
Zika IgM antibody  Plaque-reduction neutralizing antibody titer (PRNT)	Non-detectable <sup>4</sup> Zika PRNT (e.g., <10) & Detectable or non-detectable <sup>4</sup> dengue or other flavivirus PRNT	No evidence of infection with any of the viruses listed. Positive IgM ELISA result with Zika viral antigen was not confirmed by neutralization assay, which suggests that this reactivity is nonspecific.	If dengue IgM antibodies is positive, may represent a dengue case. Please refer to the dengue case definition for possible classification as a dengue case.	Not a Zika case	No

<sup>&</sup>lt;sup>1</sup> In Virginia, the Division of Consolidated Laboratory Services (DCLS) is testing for Zika virus using Zika MAC-ELISA and Trioplex Real-time RT-PCR Assay under Emergency Use Authorization. Fact sheets for healthcare providers and patients for Zika MAC-ELISA and Trioplex Real-time RT-PCR Assay are available at <a href="http://www.cdc.gov/zika/state-labs/index.html">http://www.cdc.gov/zika/state-labs/index.html</a>

<sup>&</sup>lt;sup>2</sup>The pregnancy registry was established by CDC to collect information about Zika virus infection during pregnancy and congenital Zika virus infection. The registry includes pregnant women with positive or inconclusive Zika test results, regardless of whether they have symptoms, and prenatally or perinatally exposed infants born to these women, including infants with congenital Zika virus infection. Link to CDC's Pregnancy Registry: <a href="http://www.cdc.gov/zika/hc-providers/registry.html">http://www.cdc.gov/zika/hc-providers/registry.html</a>.

<sup>&</sup>lt;sup>3</sup>Does not meet the CSTE interim Zika case definition laboratory criteria, but Zika virus cannot be ruled out

<sup>&</sup>lt;sup>4</sup> PRNT minimal level of detection is ≥20